

Application No. 10/055743
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Amendment
Attorney Docket No. S63.2B-9964-US01

Remarks

Rejections

35 U.S.C. §102(b)

The rejection of claims 1, 2, 4, 5 and 8-12 as anticipated by Samuelson et al. (US 6165166) as set forth in the previous Office Action mailed June 27, 2003 has been maintained. The Office Action asserted that Samuelson et al. teaches a trilayer medical tubing for catheters, the outer layer containing polyether block amide (col. 6, line 19), the inner layer containing high density polyethylene (col. 6, line 44), and the intermediate tie layer (col. 6, line 55) joins the inner and outer layers. The Office Action further asserts that the tie layer contains a maleic acid modified olefinic material (col. 7, lines 31-43).

Claim 1 has been amended to incorporate the limitations of claims 2 and 3 which have been canceled. Claim 1 as amended is directed to an embodiment having a tie layer which is a blend of at least a first polymeric material and a second polymeric material wherein the first polymeric material is compatible with the material of the first tubular member and the second polymeric material is compatible with the material of the second tubular member.

Samuelson et al. describe trilayer, extruded, medical tubing comprising an outer layer, a core layer, and an intermediate tie layer. The outer layer comprises a polymer that is directly bondable, while the core layer comprises a lubricious polymer (Abstract).

Samuelson et al. suggest functionalized polymers for use in the tie layer.

Samuelson et al. make no suggestion to employ blends of polymers, at least one of which is compatible with the inner layer and at least one of which is compatible with the outer layer, as a tie layer between the inner and outer layer.

Thus, claim 1 is patentable over Samuelson et al. Claims 8-12 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable.

Claim 5 has been rewritten in independent form, incorporating the limitations of claims 1 and 4 as originally presented. Claim 5 is directed to an embodiment of a medical device in which the tie layer is provided at predetermined, discrete locations comprising only a part of the portion of the length of the medical device in which the tubular members overlap.

Claim 5 is seen as being patentable over Samuelson et al.

In order to maintain a rejection under 35 U.S.C. §102(b), each and every claim

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limitation must be met by the reference. Samuelson et al. do not describe all of the limitations as found in claims 1 and 5 as amended.

Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4, 5 and 8-12 under 35 U.S.C. §102(b) as being anticipated by Samuelson et al.

35 U.S.C. §103(a)

The rejection of claims 3, 13 and 23-25 under 35 U.S.C. §103(a) as being unpatentable over Samuelson et al. in view of Graham et al. (S 4602058), as recited in section 17 of Paper No. 4, i.e. the Office Action mailed June 27, 2003, has been maintained for the reasons of record. In that Office Action, it was asserted that Samuelson et al., at col. 4, lines 33-37, teach that the intermediate layer contain a material containing functionality to make it capable of adhering to both the outer and inner ("core") layers, but fails to teach the use of blends of polyamides and polyethylenes, or polymers compatible therewith, in the layers for its trilayer tubing. Graham teaches that blends of polyamides (col. 1, lines 17-31) and polyolefins based on polyethylene (col. 1, line 64 through col. 2, line 3) in bonding layers for laminates (col. 12, lines 60-67).

Claim 1 has been amended to incorporate the limitations of claims 2 and 3 which have been canceled. No new matter has been added.

Graham, US 4602068

Graham describes the compatibility and thermal stability of blends of polyamides/carboxyl containing ethylene polymers which is improved by adding thereto an organic carboxylic acid compound, especially di-basic acids such as sebacic acid or tartaric acid. In particular, Graham describes the inclusion of low molecular weight, low melting mono-, di-, or multi-functional organic acids (e.g. sebacic acid) to improve compatibility and inhibit "interactive cross-linking" between the polyamide and the ethylene carboxyl-containing copolymer (Col. 3, lines 35-40).

Graham states that it is known that one can prepare blends of carboxyl-containing ethylene copolymers with polyamide resins to obtain such properties as high modulus, toughness, and elongation or to obtain superior adhesive properties for use in various hot melt adhesive and

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coating applications. However, these blends are limited due to inherent thermal instability and incompatibility of each of the components. In the molten state, the amine-functionality of the polyamide is free to react with pendant carboxyl groups on the polymer forming a crosslink. The results are gel formation and high viscosities, rendering the formulations useless (Col. 3, lines 60-68 and col. 4, lines 1-4).

Thus, Graham includes the low molecular weight dicarboxylic acids in the formulation to limit the reaction between the polyamides and the EAA copolymer (Col. 4, lines 54-57).

Thus, Graham is teaching a method of improving the stability of a blend of polyamides/carboxyl containing ethylene polymers by adding low molecular weight dicarboxylic acids to the blend. Graham admits that polyamide/carboxyl containing ethylene polymer blends are known for use as hot melt adhesives, and Applicants have not suggested that such hot melt adhesives are not known.

Graham does not, however, suggest employing the compositions described therein as tie layers between tubular members or substrates in the formation of medical devices. Furthermore, Graham makes no suggestion to employ the polymer composition described therein between two substrates such that there exists a polymer in the blend which is compatible with one substrate and another polymer in the blend compatible with the other substrate.

Samuelson et al., US 6165166

Samuelson et al. describe trilayer, extruded, medical tubing comprising an outer layer, a core layer, and an intermediate tie layer. The outer layer comprises a polymer that is directly bondable, while the core layer comprises a lubricious polymer (Abstract).

Samuelson et al. suggest functionalized polymers for use in the tie layer.

Samuelson et al. make no suggestion to employ blends of polymers, at least one of which is compatible with the inner layer and at least one of which is compatible with the outer layer, as a tie layer between the inner and outer layer.

As Samuelson et al. make no suggestion to employ a blend as a tie layer, and Graham make no suggestion to employ such a blend as described therein as a tie layer between two different substrates in a medical device, and to select polymers such that there exists in the

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blend, one polymer which is compatible with each substrate, Applicants submit that this combination of references does not arrive at the present invention as found in claims 1, as amended, 13 and 23-25.

Applicants respectfully request withdrawal of claims 3, 13 and 23-25 under 35 U.S.C. §103(a) as being obvious over Samuelson et al. (US 6165166) in view of Graham (US 4602058).

Additionally, claim 9 has been amended. Support is found on page 6, first full paragraph. No new matter has been added.

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CONCLUSION

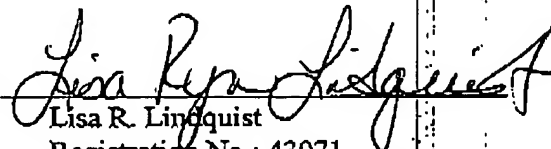
Applicants have addressed each of the issues presented in the Office Action. Claims 1, 4-13 and 23-25 are pending in the Application. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented.

Respectfully submitted,

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